



IPW

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: May 12, 2004

Signature: Lynn L. Janulis

(Lynn L. Janulis)

Docket No.: 01017/40006  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Steven S. Gill et al.

Application No.: 10/784,547

Filed: February 23, 2004

Art Unit: 1614

For: METHOD OF TREATING PARKINSON'S  
DISEASE IN HUMANS BY  
INTRAPUTAMINAL INFUSION OF GLIAL  
CELL-LINE DERIVED NEUROTROPHIC  
FACTOR

Examiner: Not Yet Assigned

### INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.56, the attention of the United States Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

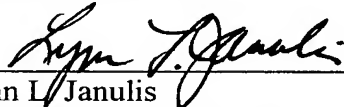
The Applicants request that the documents listed on the attached Form PTO/SB/08 be made of official record in the above-identified application and considered by the Examiner. Copies of all listed documents cited on Form PTO/SB/08 are submitted herewith. While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 C.F.R. § 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein constitutes prior art under 35 U.S.C. §§ 102 or 103.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. § 1.56(a) exists. It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98.

No fee is believed to be due under 37 C.F.R. § 1.97(b) because this statement and Form PTO/SB/08 are being submitted before receipt of a first Office action on the merits in the above-identified patent application. Should the Patent Office determine that a fee is due for consideration of this Information Disclosure Statement, however, the Patent Office is hereby authorized to charge that fee to Deposit Account 13-2855. A copy of this paper is enclosed.

Dated: May 12, 2004

Respectfully submitted,

By   
Lynn L. Janulis  
Registration No.: 53,066  
MARSHALL, GERSTEIN & BORUN LLP  
233 S. Wacker Drive, Suite 6300  
Sears Tower  
Chicago, Illinois 60606-6357  
(312) 474-6300

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/784,547	
			Filing Date	February 23, 2004	
			First Named Inventor	Steven S. Gill	
			Art Unit	1614	
			Examiner Name	Not Yet Assigned	
Sheet	1	of	2	Attorney Docket Number	01017/40006

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	6,042,549	03-28-2000	Medtronic, Inc.	
	A2	6,362,319	03-26-2002	Amgen Inc.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	B1	WO 93/06116	04-01-1993	Syntex-Synergen Neuroscience Joint Venture		
	B2	WO 03/007785	01-30-2003	Microvention, Inc.		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
	C1	Al et al., "Intraputaminal infusion of GDNF in aged rhesus monkeys: distribution and dopaminergic effects," <i>J. Comp. Neurol.</i> , 461:250-261 (2003).	✓	
	C2	BJÖRKLUND et al., "Towards a neuroprotective gene therapy for Parkinson's disease: use of adenovirus, AAV and lentivirus vectors for gene transfer of GDNF to the nigrostriatal system in the rat Parkinson model," <i>Brain Research</i> , 886:82-98 (2000).	✓	
	C3	BJÖRKLUND et al., "Parkinson disease gene therapy moves toward the clinic," <i>Nature Med.</i> , 6:1207-1208 (2000).	✓	
	C4	BOWENKAMP et al., "6-hydroxydopamine induces the loss of the dopaminergic phenotype in substantia nigra neurons of the rat: a possible mechanism for restoration of the nigrostriatal circuit mediated by glial cell line-derived neurotrophic factor," <i>Exp. Brain Res.</i> , 111:1-7 (1996).	✓	
	C5	CHOI-LUNDBERG et al., "Dopaminergic neurons protected from degeneration by GDNF gene therapy," <i>Science</i> , 275:838-841 (1997).	✓	
	C6	CONNOR et al., "Differential effects of glial cell line-derived neurotrophic factor (GDNF) in the striatum and substantia nigra of the aged Parkinsonian rat," <i>Gene Therapy</i> , 6:1936-1951 (1999).	✓	
	C7	GASH et al., "Functional recovery in parkinsonian monkeys treated with GDNF," <i>Nature</i> , 380:252-255 (1996).	✓	
	C8	GASH et al., "Neuroprotective and neurorestorative properties of GDNF," <i>Ann. Neurol.</i> , 44:S121-S125 (1998).	✓	
	C9	GRONDIN et al., "Chronic intracerebral delivery of trophic factors via a programmable pump as a treatment for Parkinsonism," <i>Methods in Molecular Medicine</i> , 62:257-267 (2001).	✓	
	C10	GRONDIN et al., "Chronic, controlled GDNF infusion promotes structural and functional recovery in advanced parkinsonian monkeys," <i>Brain</i> , 125:2191-2201 (2002).	✓	
	C11	GRONDIN et al., "Glial cell line-derived neurotrophic factor increases stimulus-evoked dopamine release and motor speed in aged rhesus monkeys," <i>J. Neurosci.</i> , 23:1974-1980 (2003).	✓	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/784,547
				Filing Date	February 23, 2004
				First Named Inventor	Steven S. Gill
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	01017/40006

C12	HOU et al., "Glial cell line-derived neurotrophic factor exerts neurotrophic effects on dopaminergic neurons <i>in vitro</i> and promotes their survival and regrowth after damage by 1-methyl-4-phenylpyridinium," <i>J. Neurochem.</i> , 66:74-82 (1996).	✓
C13	KEARNS et al., "GDNF protects nigral dopamine neurons against 6-hydroxydopamine <i>in vivo</i> ," <i>Brain Research</i> , 672:104-111 (1995).	✓
C14	KIRIK et al., "Long-term rAAV-mediated gene transfer of GDNF in the rat Parkinson's model: intrastriatal but not intranigral transduction promotes functional regeneration in the lesioned nigrostriatal system," <i>J. Neurosci.</i> , 20:4686-4700 (2000).	✓
C15	KIRIK et al., "Delayed infusion of GDNF promotes recovery of motor function in the partial lesion model of Parkinson's disease," <i>Eur. J. Neuroscience</i> , 13:1589-1599 (2001).	✓
C16	KIRIK et al., "Localized striatal delivery of GDNF as a treatment for Parkinson Disease," <i>Nature Neuroscience</i> , 7:105-110 (2004).	✓
C17	KORDOWER et al., "Neurodegeneration prevented by lentiviral vector delivery of GDNF in primate models of Parkinson's disease," <i>Science</i> , 290:767-773 (2000).	✓
C18	LINDVALL et al., "Clinical observations after neural transplantation in Parkinson's disease," <i>Prog. Brain Res.</i> , 127:299-320 (2000).	✓
C19	LIN et al., "GDNF: a glial cell-line derived neurotrophic factor for midbrain dopaminergic neurons," <i>Science</i> 260:1130-1132 (1993).	✓
C20	LIN et al., "Purification and initial characterization of rat B49 glial cell line-derived neurotrophic factor," <i>J. Neurochem.</i> , 63:758-768 (1994).	✓
C21	MA et al., "Dyskinesia after fetal cell transplantation for Parkinsonism: a PET study," <i>Ann. Neurol.</i> 52:628-634 (2002).	✓
C22	MASWOOD et al., "Effects of chronic intraputamenal infusion of Glial cell line-derived neurotrophic factor (GDNF) in aged Rhesus monkeys," <i>Neurobiology of Aging</i> , 23:881-889 (2002).	✓
C23	OLSON et al., "Nerve growth factor affects <sup>11</sup> C-nicotine binding, blood flow, EEG, and verbal episodic memory in an Alzheimer patient," <i>J. Neural Transm.</i> , 4:79-95 (1992).	✓
C24	OLSON et al., "Intraputamenal infusion of nerve growth factor to support adrenal medullary autografts in Parkinson's disease," <i>Arch. Neurol.</i> , 48:373-381 (1991).	✓
C25	ROSENBLAD et al., "Intrastriatal glial cell line-derived neurotrophic factor promotes sprouting of spared nigrostriatal dopaminergic afferents and induces recovery of function in a rat model of Parkinson's disease," <i>Neuroscience</i> , 82:129-137 (1998).	✓
C26	SHULTS et al., "Intrastriatal injection of GDNF attenuates the effects of 6-hydroxydopamine," <i>NeuroReport</i> , 7:627-631 (1996).	✓
C27	TOMAC et al., "Protection and repair of the nigrostriatal dopaminergic system by GDNF <i>in vivo</i> ," <i>Nature</i> , 373:335-339 (1995).	✓
C28	TOMAC et al., "Retrograde axonal transport of glial cell line-derived neurotrophic factor in the adult nigrostriatal system suggests a trophic role in the adult," <i>Proc. Natl. Acad. Sci. (USA)</i> , 92:8274-8278 (1995).	✓
C29	WENNING et al., "Short- and long-term survival and function of unilateral intrastriatal dopaminergic grafts in Parkinson's disease," <i>Ann. Neurol.</i> , 42: 95-107 (1997).	✓
C30	ZHANG et al., "Dose response to intraventricular glial cell line-derived neurotrophic factor administration in Parkinsonian monkeys," <i>J. Pharmacol. Exp. Ther.</i> , 282:1396-1401 (1997).	✓

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--